UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA, Plaintiff, v. TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, a corporation; and MARK A. SUTTER and MARK LINCOLN, individuals, Defendants.	)	Civil No. 11-11179 Hon. Victoria A. Roberts

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Terumo Cardiovascular Systems Corporation ("TCVS"), located in Ann Arbor, Michigan, and Mark A. Sutter (TCVS's President and Chief Executive Officer), and Mark Lincoln (TCVS's Vice President of Quality Assurance and Operations, who assumed this position on September 17, 2010) (collectively, "Defendants"), alleging the following:

(1) Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are (a) adulterated within the meaning of 21 U.S.C.

§ 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with the current good manufacturing practice ("CGMP") requirements for devices, see 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820 (the Quality System ("QS") regulation); and (b) misbranded within the meaning of 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish information or material respecting their devices, as set forth in 21 U.S.C. § 360i and the medical device reporting ("MDR") regulation, 21 C.F.R. Part 803;

(2) Defendants violate the Act, 21 U.S.C. § 331(k), by doing acts that result in the adulteration, within the meaning of 21 U.S.C. § 351(h), of articles of device, as defined by 21 U.S.C. § 321(h), while such devices are held for sale after the shipment of one or more of their components in interstate commerce; and

(3) Defendants violate the Act, 21 U.S.C. § 331(e), by failing to maintain and/or submit reports respecting their devices, as required by 21 U.S.C. § 360i; and

Defendants, without admitting or denying the allegations of the Complaint, having appeared and having consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. § 1345.

2. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c).

3. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act").

4. For purposes of this Decree, the following definitions shall apply:

A. "Ann Arbor Facility" shall refer to the TCVS manufacturing facility located at 6200 Jackson Road, Ann Arbor, Michigan.

B. "Ann Arbor Manufacturing Operations" shall refer to the manufacturing, processing, packing, labeling, storing, holding, installing, and distributing of all devices at or from the Ann Arbor Facility.

C. "Cardiovascular Devices" shall mean all the devices that are manufactured, packed, distributed, and/or held for sale by TCVS at or from the Ann Arbor Facility, including, but not limited to, cardiopulmonary bypass devices (heart-lung devices), air bubble detectors, level monitors, flow monitors, pressure

monitors, temperature monitors, gas monitors, central control monitors, roller pumps, centrifugal control units, centrifugal drive motors, electronic oxygen blenders and analyzers, blood-parameter monitors and calibrators, venous occluders, cables, stainless steel connectors, electronic patient gas system oxygen sensors, intraoperative monitoring systems, reducers, cannula prime lines, cooling and heating devices, data management systems, hematocrit/oxygen saturation monitoring systems, cannulae, catheters, and accessories for disposable devices (as defined in Paragraph 4.G), including, but not limited to, accessories for myocardial protection products and bubble traps. "Cardiovascular Devices" shall exclude the Makino V33 and V34 vertical mills and Makino SP43 wire Electrical Discharge Machining ("EDM") equipment that are kept in a separate room at the Ann Arbor Facility, are segregated from TCVS's equipment, and are used solely by Terumo Heart Incorporated ("THI") for manufacturing THI's devices and not TCVS's Cardiovascular Devices.

D. A device is "medically necessary" if (i) it is used to treat or prevent a serious disease or medical condition; (ii) there is no other available source of that product or alternative product that is judged by FDA to be an adequate substitute; and (iii) an authorized representative (i.e., Chief Executive

Officer, President, Chief Medical Officer, Chief Operating Officer, Director of Operating Room, Chief Perfusionist, or Hospital Administrator) of TCVS's existing US users and/or existing international end-users (as those terms are defined in Paragraph 4.H) after reviewing the Notification Guide referenced in Paragraph 4.I, signs a form approved by FDA certifying that s/he is aware of FDA's findings and deems the device necessary in performing cardiopulmonary bypass ("CPB") procedures (hereafter, "Certificate of Medical Necessity").

E. A device listed below is deemed to satisfy the requirements of Paragraph 4.D(i)-(ii) and becomes "medically necessary" for a particular existing US user and/or existing international end-user when an authorized representative of that user has signed the Certificate of Medical Necessity ("CMN") described in Paragraph 4.D(iii) for such device:

(1) Centrifugal control unit (cleared under K915363);

(2) Centrifugal drive motor (cleared under K882758);

(3) TCVS tubing clamp that communicates electronically with the CPB machine console;

(4) Air bubble detector, level monitor, flow monitor, pressure monitor, and temperature monitor (cleared under K915183); and

(5) TCVS cable that communicates electronically with the CPB machine console.

F. "Days" shall refer to calendar days unless otherwise stated.

G. "Disposable Devices" shall mean non-hardware devices that are discarded after each use, namely, tubing, cannulae (excluding the TenderFlow™ Pediatric Arterial Cannula, cleared under K063618), catheters, connectors, sensors, oxygenators, filters, reservoirs, disposable pump heads, vents, and suckers.

H. "Existing US User" means a particular domestic facility, hospital, and/or group of perfusionists or surgeons that at the time of entry of this Decree: (i) owned Cardiovascular Devices; and (ii) was in existence, and is limited to the particular Cardiovascular Devices that the particular domestic facility, hospital, and/or group of perfusionists or surgeons owned prior to such time.

"Existing International Distributor" means a particular overseas first-level distributor that at the time of entry of this Decree: (i) had purchased Cardiovascular Devices directly from TCVS; and (ii) was in existence, and is limited to the particular Cardiovascular Devices that the particular overseas first-level distributor had purchased prior to such time.

"Existing International End-User" means a particular overseas facility, hospital, and/or group of perfusionists or doctors that at the time of entry of this Decree: (i) had purchased Cardiovascular Devices directly or indirectly from a particular existing international distributor; and (ii) was in existence, and is limited to the particular Cardiovascular Devices that the particular overseas facility, hospital, and/or group of perfusionists or surgeons had purchased from the particular existing international distributor prior to such time.

I. "Notification Guide" shall refer to the document developed by Defendants, and reviewed and approved by FDA, that notifies TCVS's existing US users and existing international end-users of FDA's findings at the Ann Arbor Facility, so that they may make an informed decision concerning whether to continue to use TCVS's devices or to transition to alternative, legally-marketed products. The Notification Guide (attached hereto as Exhibit 1 and incorporated by reference herein) contains, among other information, the CMN referenced in Paragraph 4.D(iii). One year after entry of this Decree and every six months thereafter until Defendants receive FDA's notification under Paragraph 5.G, Defendants shall send their existing US users and existing international end-users whose authorized representatives have signed the CMN a letter, reviewed and approved by FDA, that

updates the users on the status of the Ann Arbor Facility's compliance or non-compliance with the requirements of this Decree, the Act, and the QS and MDR regulations.

J. "Product Revenue" shall refer to the total revenue derived from all sales (including, but not limited to, domestic, international, and intercompany sales) and services of all Cardiovascular Devices.

K. "Support" shall mean that TCVS may provide existing US users and existing international distributors with the following for the particular Cardiovascular Device(s) owned by the existing US users and/or purchased by the existing international distributors at the time of entry of the Decree: (1) service and maintenance, including corrective and preventive actions under 21 C.F.R. § 820.100; (2) replacement devices (including parts, accessories, and components); TCVS may not provide to any existing US users and/or existing international distributors the CDI 101 blood parameter monitor until that device has been cleared by FDA; and (3) loaner devices. Notwithstanding the foregoing: (4) TCVS may provide to existing US users and existing international distributors CDI 500 loaner devices to replace CDI 101 devices until the CDI 101 has been cleared by FDA, and (5) TCVS may provide up to twelve (12) total loaner heart-lung systems per calendar year to enable existing US

users to expand their services in existing facilities; and (6) TCVS may export the devices listed in Paragraph 8.G to enable existing international end-users to expand their services in existing facilities, provided that (a) the number of each type of device distributed per calendar year for this purpose does not exceed 20 percent of the specific cap set forth in Paragraph 8.G(4) for that device; and (b) the total number of any type of device exported per calendar year under Paragraph 8.G for any purpose shall not exceed the cap for that device set forth in Paragraph 8.G(4).

INJUNCTIVE PROVISIONS

5. Except as provided in Paragraph 8 of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently enjoined under 21 U.S.C. § 332(a) from manufacturing, packing, storing, installing, and distributing any device at or from the Ann Arbor Facility unless and until:

A. TCVS's facilities, methods, processes, and controls used to manufacture, process, pack, label, hold, and distribute devices at or from the Ann Arbor Facility and/or any new facility

are established, operated, and administered in conformity with the applicable laws and regulations including, but not limited to, 21 U.S.C. §§ 351(h) and 352(t)(2), and the QS and MDR regulations, 21 C.F.R. Parts 803 and 820. Specifically, Defendants shall take the following actions, among others:

(1) Establish and maintain adequate written rework procedures, which shall include retesting and reevaluation of the nonconforming product(s) after rework to ensure that the product(s) meet current approved specifications;

(2) Establish and maintain adequate written quality requirements that must be met by contractors, suppliers, and consultants, and adequate written procedures to ensure that all purchased or otherwise received components and services conform to specified requirements;

(3) Validate processes whose results cannot be fully verified by subsequent inspection and testing;

(4) Establish and implement adequate written design validation requirements to ensure that devices conform to defined user needs and intended uses;

(5) Establish and maintain adequate written procedures for corrective and preventive actions (“CAPAs”) and documenting those activities;

(6) Maintain accurate and complete complaint files and establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints; and

(7) Develop and implement adequate written MDR procedures in compliance with 21 C.F.R. Part 803, and ensure that employees are trained on and understand the MDR requirements and procedures.

B. Defendants retain, at TCVS's expense, an independent person or persons (the "expert") to inspect the Ann Arbor Facility and review its manufacturing procedures and records to determine whether the methods, facilities, and controls are operated and currently administered in conformity with this Decree, the Act, and the QS and MDR regulations. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement) to Defendants or their families. Defendants shall notify FDA in writing of the identity of the expert and his or her qualifications within fifteen (15) days of retaining such expert. The expert shall:

(1) Perform a comprehensive inspection of the methods and controls used to manufacture devices at the Ann Arbor Facility and determine whether they are in compliance with this Decree,

the Act, and the QS and MDR regulations; in conducting this inspection, the expert shall review all CGMP and MDR deviations at the Ann Arbor Facility brought to Defendants' attention in writing since May 2004 by FDA (including, but not limited to, all Forms FDA-483 issued to TCVS for the Ann Arbor Facility), by the expert, or by any other source;

(2) Within thirty (30) days of completing the inspection referenced in subparagraph 5.B(1), the expert shall submit simultaneously to FDA and Defendants a complete written report prepared by the expert identifying in detail which processes, controls, procedures, and FDA-483 observations the expert inspected and the expert's evaluation as to whether each such procedure, system, and observation has, or has not, been corrected; and delineate the identification of any additional failures to meet the requirements of the Decree, the Act, and the QS and MDR regulations;

C. Within thirty (30) days of receiving the expert's inspection report(s) under Paragraph 5.B(2), Defendants shall submit a written report ("work plan") to FDA detailing the specific actions Defendants have taken and/or will take to address the expert's observations and bring the Ann Arbor Facility's methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute devices into

compliance with the requirements of this Decree, the Act, and the QS and MDR regulations. The specific actions in the work plan shall be set forth in numbered steps and, where appropriate, the numbered steps may include subordinate lettered steps. The work plan shall include a timetable with specific dates for completing each numbered step and may include, where appropriate, interim dates for completing subordinate lettered steps. The work plan, including its proposed specific actions and timetable, shall be subject to FDA approval. Defendants shall ensure the implementation of the numbered steps in the work plan in accordance with the timetable approved by FDA, and FDA will approve or disapprove in writing the proposed work plan within thirty (30) business days; and

D. As the actions detailed in the work plan are completed, Defendants shall notify the expert in writing, who shall promptly inspect and verify whether those actions have been completed in a manner that complies with the requirements of this Decree, the Act, and the QS and MDR regulations to the expert's satisfaction and in accordance with the work plan timetable approved by FDA.

If the expert determines that an action has not been completed to his or her satisfaction, the expert shall promptly notify Defendants in writing. Beginning thirty (30) days after

approval of the work plan by FDA, and quarterly thereafter, the expert shall submit to FDA a table that summarizes the expert's findings regarding whether the actions have been completed to the expert's satisfaction and in accordance with the numbered steps in the work plan timetable. FDA may, in its discretion and without prior notice, periodically inspect the Ann Arbor Facility and undertake such additional examinations, reviews, and analyses as FDA deems appropriate to verify whether the actions reported to have been completed have in fact been adequately completed on time. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA.

E. When the expert determines that all of the actions identified in the work plan approved by FDA have been completed to his or her satisfaction, the expert shall provide Defendants and FDA with a written certification that all of the actions have been completed and that, based on the inspection conducted under Paragraph 5.B and on the satisfactory completion of the actions in the work plan identified under Paragraph 5.C, Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute the Cardiovascular Devices

are and, if properly maintained and implemented by Defendants, will continuously remain in conformity with the requirements of this Decree, the Act, and the QS and MDR regulations. The expert's certification shall include a full and complete detailed report of the results of his or her inspection.

The expert may provide FDA up to three (3) separate certifications under this paragraph, provided that:

(1) The first certification certifies that the facilities, methods, processes, and controls generally applicable to all Cardiovascular Devices (the "general systems") are operated in conformity with the requirements of this Decree, the Act, and QS and MDR regulations, and includes a detailed description of the actions that Defendants have taken to achieve compliance;

(2) The second certification certifies that the expert has inspected both the general systems and the specific methods, processes, and controls applicable to the devices listed in Paragraph 4.E and that all CGMP and MDR deviations at the Ann Arbor Facility for these devices have been corrected and are in compliance with the requirements of this Decree, the Act, and QS and MDR regulations. The expert may provide this certification in two stages for no more than two groups of devices; and

(3) The third certification certifies that the expert has inspected both the general systems and the specific methods,

processes, and controls applicable to the production of all other devices not listed in Paragraph 4.E ("All Other Products") and that all CGMP and MDR deviations at the Ann Arbor Facility for All Other Products have been corrected and are in compliance with the requirements of this Decree, the Act, and QS and MDR regulations.

The certification(s), report(s), and records required by this paragraph, as well as all other communications required to be sent to FDA under this Decree, shall be prominently marked "Terumo Cardiovascular Systems Corporation Decree Correspondence" and sent to the District Director of FDA's Detroit District Office, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207; and

F. Within forty-five (45) business days of FDA's receiving the expert's certification(s) under Paragraph 5.E that the specific actions set forth in each work plan submitted by Defendants under Paragraph 5.C have been completed to the expert's satisfaction, duly authorized FDA representatives may inspect, as FDA deems necessary and without prior notice, the Ann Arbor Facility, including buildings, equipment, personnel, finished and unfinished materials, containers, and labeling, and all records relating to the methods used in, and the facilities and controls used for, the manufacture, design, processing,

packing, storage, installation, and distribution of devices, to determine whether the requirements of Paragraphs 5.A-E of this Decree have been met, and whether the Ann Arbor Facility is otherwise operating in conformity with this Decree, the Act, and the QS and MDR regulations;

If FDA determines that Defendants are not operating in conformity with the requirements of this Decree, the Act, and QS and MDR regulations, FDA will notify Defendants of the deficiencies it observed and take any other action FDA deems appropriate (e.g., issuing an order pursuant to Paragraph 11). Within thirty (30) days of receiving this notification from FDA, Defendants shall submit to FDA a plan describing the actions Defendants propose to take and a timetable for correcting the deficiencies. The timetable and plan shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA-approved timetable and plan, and cause the expert to reinspect the conditions relevant to the deficiencies noted by FDA and either:

(1) certify that the deficiencies have been corrected to ensure that Defendants' methods, facilities, processes, and controls used for manufacturing, processing, packing, holding, and distributing the Cardiovascular Devices are in conformity

with the requirements of this Decree, the Act, and QS and MDR regulations; or

(2) notify Defendants and FDA in writing that one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, Defendants shall correct the deficiencies to the expert's satisfaction, at which point the expert shall issue the certification simultaneously to Defendants and FDA.

Within forty-five (45) business days after FDA receives the certification, FDA may reinspect as it deems necessary without prior notice; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 5.A-F.

6. After Defendants receive the FDA notice described in Paragraph 5.G of this Decree, Defendants and each of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, shall be permanently enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by doing or causing introduction, and delivery for introduction, into interstate commerce of any device, as defined by 21 U.S.C. § 321(h), that is adulterated, within the meaning of 21 U.S.C. § 351(h), or misbranded, within the meaning of 21 U.S.C. § 352(t)(2);

B. Violates 21 U.S.C. § 331(k) by doing or causing any act that results in the adulteration, within the meaning of 21 U.S.C. § 351(h), of any device, as defined by 21 U.S.C. § 321(h), while such device is held for sale after the shipment of one or more of its components in interstate commerce; and

C. Violates 21 U.S.C. § 331(e) by doing or causing the failure to maintain and/or submit reports respecting devices, defined by 21 U.S.C. § 321(h), as required by 21 U.S.C. § 360i.

If, and for as long as, an individual Defendant or an employee of TCVS ceases to be employed by or act on behalf of TCVS or any of its subsidiaries, franchises, affiliates and/or "doing business as" entities, then that Defendant or employee shall not be subject to the terms of this Decree except as to such individual's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or to act on behalf of TCVS or its subsidiaries, franchises, affiliates, and/or "doing business as" entities.

7. Defendants shall not transfer any of the Ann Arbor Manufacturing Operations to any other manufacturing site ("new site(s)") unless and until (1) they propose to FDA a written plan for the transfer, (2) FDA reviews and approves the proposal in writing, and (3) Defendants' expert has certified in writing to FDA that he or she has inspected the new facility and that, in his or her opinion, the methods, facilities, processes, and controls used to manufacture, process, pack, hold, install, and distribute devices at or from any new site(s) are in compliance with this Decree, the Act, and the QS and MDR regulations. FDA reserves the right to inspect the new site(s) as and when it deems necessary and without prior notice.

EXCLUSIONS

8. Notwithstanding Paragraph 5, Defendants may engage in the following activities at the Ann Arbor Facility for: (1) existing US users who have submitted a CMN, provided that Defendants submit such CMN to FDA within forty-five (45) days after the Court enters this Decree; and (2) existing international distributors , provided that their existing international end-users have submitted a CMN to TCVS, and TCVS has complied with Paragraph 8.G(2).

A. Defendants may continue to support TCVS's existing US users and existing international distributors with respect to

medically necessary devices and/or the other Cardiovascular Devices listed in Exhibit 2 for which authorized representatives of the existing US users and/or existing international end-users have signed a CMN, provided that:

(1) Defendants shall maintain a record, and shall allow FDA access to such record upon request, of all such requests, orders, and associated shipping documents, which shall include the following information:

(a) a detailed description of the requested order, service, maintenance, replacement, or loaner, including a description of the malfunction or performance issue(s) that gave rise to the request, if any;

(b) the date of any such request;

(c) the date(s) of service, maintenance, replacement, or loaner installation;

(d) the names, addresses, and telephone numbers of the persons/entities making any such request; and

(e) a detailed description of TCVS components, parts, or accessories used to provide service, maintenance, replacement, or satisfy a loaner request; and

The parties understand that TCVS will exercise its best efforts to obtain the information described in Paragraph 8.A(1) from existing international distributors, and in the event such

distributor(s) does not provide such information, TCVS will not provide further support to such distributor(s).

(2) At any time, FDA may, in its discretion and in writing, expand or revoke its authorization to Defendants under this paragraph. If FDA decides to revoke its authorization to Defendants with respect to any Cardiovascular Device, FDA will notify Defendants in writing of its decision to revoke such authorization and the reasons and information supporting such decision. Defendants will have an opportunity to respond in writing and, if necessary, meet with representatives of the Center for Devices and Radiological Health to discuss that decision. FDA's decision following such a meeting shall be final and not reviewable;

B. Defendants may manufacture, process, and distribute, test, verify, or validate design changes of any Cardiovascular Device, including any component or accessory, that is manufactured, processed, packed, held for sale, or distributed solely for the purpose of continuing to implement a field corrective action or recall;

C. Defendants may (i) install Cardiovascular Devices, including any components, parts, or accessories that were already in the possession of Defendants' existing US users and/or (ii) ship such devices to existing international distributors that had

been purchased by such distributors prior to entry of this Decree;

D. Unless and until notified otherwise by FDA under Paragraph 8.A(2) and/or Paragraph 11.A, Defendants also may continue to sell and/or distribute to existing US users and/or existing international distributors (1) all TCVS models of Disposable Devices (except the TenderFlow™ Pediatric Arterial Cannula, cleared under K063618) that were marketed legally at the time of entry of this Decree and that have not been changed or modified since entry of this Decree in their intended use or in any other way that could significantly affect their safety or effectiveness; (2) replacement units (including their parts, components, and accessories) to existing US users and/or existing international distributors to support medically necessary devices and other Cardiovascular Devices listed in Exhibit 2; (3) brackets for tubing packs and heart-lung machines; and (4) sternal saws and replacement blades. However, Defendants may not sell and/or distribute any device to any existing international distributor unless the device is intended for an existing international end-user who owned such a device prior to the date of entry of this Decree.

E. Defendants may conduct research and development activities for Cardiovascular Devices and distribute such devices

for research purposes only, such as research in laboratories, provided that the devices are labeled “For Research Only - Not for Human Use.”

F. Defendants may distribute from the Ann Arbor Facility any medical devices: (i) that are not manufactured, packed, processed, and/or labeled at the Ann Arbor Facility, and (ii) for which the Ann Arbor Facility conducts no post-marketing activities.

G. Defendants may export any medically necessary devices and any Cardiovascular Devices listed in Exhibit 2 to support their existing international distributors, provided that:

(1) the existing international end-users have given TCVS a signed CMN;

(2) TCVS, using the email and telephone number information provided on these CMN forms, exercises its best efforts to confirm that the person signing the CMN form has read the form and is who s/he purports to be;

(3) TCVS documents these efforts and submits the documents and CMN forms to FDA within five (5) days of receipt; and

(4) the total number of Cardiovascular Devices exported under this subparagraph shall be limited per calendar year as follows: APS-1 systems (80 units); Sarns 8000 systems (35 units); heater and cooler management systems (63 units); CDI 500

blood parameter monitors (100 units); CDI 101 blood parameter monitors (27 units, provided that the CDI 101 has been cleared by FDA); and centrifugal drive motors (33 units). Defendants shall maintain records evidencing compliance with this subparagraph for two years following each such export.

Defendants may also export the Evolution Portable Emergency Bypass System, after this device has been cleared by FDA, provided that the device complies with all of the requirements of 21 U.S.C. §§ 381(e)(1)(A)-(D). Defendants may export any other FDA-cleared or approved device only if the device complies with all of the requirements of 21 U.S.C. §§ 381(e)(1)(A)-(D).

Defendants may export any uncleared or unapproved device only after they have obtained FDA's written permission for such export and demonstrated to FDA that the device complies with all of the requirements of 21 U.S.C. §§ 381(e)(1)(A)-(D) and 21 U.S.C. § 382(f) (substantial conformity with CGMP requirements).

ADDITIONAL REQUIREMENTS

9. After Defendants have complied with Paragraphs 5.A-E and FDA has notified them pursuant to Paragraph 5.G, Defendants shall select and retain at TCVS's expense an independent person or persons (the "auditor") to conduct audit inspections of the Ann Arbor Facility not less than once every six (6) months for a period of one (1) year and annually thereafter for an additional

period of four (4) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement) to Defendants or their immediate families and may, if Defendants choose, be the same person or persons described as the expert in Paragraph 5.B.

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the "audit report") analyzing whether Defendants are in compliance with this Decree, the Act, and the QS and MDR regulations, and identifying all deviations from this Decree, the Act, and the QS and MDR regulations ("audit report observations"). As part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the inspections are completed. In addition, Defendants shall maintain the audit reports and all underlying records in a separate file at the Ann Arbor Facility and shall make the audit reports and records available to FDA upon request.

B. If an audit report contains any audit report observation(s), Defendants shall, within thirty (30) days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of audit report observations will take longer than thirty (30) days, Defendants shall, within ten (10) days of receipt of the audit report, propose a schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days of Defendants' receipt of an audit report, or within the time period provided in a schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of the beginning of that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Ann Arbor Facility and take any other measures necessary to monitor and ensure continuing compliance with this

Decree, the Act, and the QS and MDR regulations. During such inspections, FDA representatives shall be permitted ready access to the Ann Arbor Facility including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples (without charge to FDA) of Defendants' finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, receiving, holding, installing, and distribution of any and all of TCVS's devices, including components, parts, accessories, and in-process and finished devices, in order to ensure continuing compliance with this Decree, the Act, and the QS and MDR regulations. The costs of all such inspections, record reviews, sample analyses, and FDA supervisory costs to monitor this Decree shall be borne by TCVS at the rates specified in Paragraph 23. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority granted to FDA to make inspections under the Act, 21 U.S.C. § 374.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by Defendants or an expert under this Decree, or any other information, that Defendants have at the Ann Arbor Facility failed to comply with any provision of this Decree, or have violated the Act, the QS regulation or the MDR regulation, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, and the QS and MDR regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, with respect to medical devices that are manufactured, packed, processed, and/or labeled at the Ann Arbor Facility or for which the Ann Arbor Facility conducts post-marketing activities, including, but not limited to, the following:

A. Cease all manufacturing, designing, processing, packing, storing, holding, installing, and/or distributing any or all device(s);

B. Revise, modify, expand, or extend any report(s), plan(s), or audit(s) required pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall, at Defendant TCVS's expense, specified devices released or distributed by Defendants or that are under

the custody and control of Defendants' agents, distributors, and/or users (defined in Paragraph 4.H);

E. Issue a safety alert with respect to a device manufactured, processed, packed, labeled, installed, held, or distributed by Defendants; and/or

F. Take any other corrective action(s) with respect to any device manufactured, processed, packed, labeled, held, installed, or distributed by Defendants at the Ann Arbor Facility as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and the QS and MDR regulations.

12. The following process and procedures shall apply when FDA issues an order under Paragraph 11, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days of receiving the FDA order, notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific actions taken or proposed to be taken and the proposed schedule for completing the actions; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall, within ten (10) business days

of receiving the FDA order, explain in writing the basis for their disagreement and, in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmance or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and may, if they so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made by the Court in accordance with the terms set forth in Paragraph 30 of this Decree.

D. The process and procedures set forth above in subparagraphs A-C above shall not apply to any order issued under Paragraph 11 if such order states that, in FDA's judgment, the

matter raises significant public health concerns. In such case, the Defendants shall immediately and fully comply with the terms of that order. Should the Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order.

13. Any cessation of operations or other actions described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and the QS and MDR regulations, and that Defendants may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA will determine within forty-five (45) days of receipt of the request whether Defendants appear to be in compliance and, if so, issue to Defendants a written notification permitting resumption of operations.

14. Within ten (10) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, and post a copy of this Decree in the employee common areas at the Ann Arbor Facility. Within thirty (30) days of the date of entry of this Decree, Defendants

shall provide to FDA an affidavit of compliance (signed by a person with personal knowledge of the facts) stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree pursuant to this paragraph.

15. Defendants shall notify the FDA District Director at the address specified in Paragraph 5.E(3) of this Decree at least ten (10) business days before any change in ownership or character of their business such as dissolution, assignment, bankruptcy, or sale resulting in emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of TCVS, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any proposed successor or assignee at least thirty (30) business days prior to making any assignment or transferring any interest in the company as described in this paragraph. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

16. Defendants shall provide a report to FDA describing the status of compliance with the Notification Guide two (2) years

after entry of this Decree, every six (6) months thereafter, and at such other times as FDA may request.

FINANCIAL PROVISIONS

17. Within two (2) years after entry of this Decree, TCVS shall pay the United States Treasury equitable disgorgement in the amount of thirty-five (35) million dollars ($35,000,000.00). The first payment of seventeen and a half (17.5) million dollars ($17,500,000.00) shall be made within fifteen (15) days after entry of this Decree. The second payment of seventeen and a half (17.5) million dollars ($17,500,000.00) shall be made within three hundred and sixty-five (365) days after the first payment.

18. In the event that Defendants fail, as determined either by the expert or FDA, to comply with any time frame or provision of this Decree, then FDA shall have the sole and unreviewable discretion to order TCVS to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.00) per violation of this Decree and an additional sum of fifteen thousand dollars ($15,000.00) for each day such violation continues. The amount of liquidated damages imposed under this paragraph will not exceed five (5) million dollars ($5,000,000.00) in any one calendar year.

19. In the event Defendants fail, as determined either by the expert or FDA, to satisfactorily complete one or more of the numbered steps, including the completion date for all numbered

steps, in the work plan referenced in paragraph 5.C in accordance with the FDA-approved timetable, FDA may order TCVS to pay the United States Treasury as liquidated damages the sum of fifteen thousand dollars ($15,000.000) for each incomplete numbered step, per business day (e.g., if two steps are not timely complied with for two business days, then liquidated damages will be $60,000.00), until the numbered step is fully implemented and completed to FDA's satisfaction. The amount of liquidated damages imposed under this paragraph will not exceed five (5) million dollars ($5,000,000.00) in any one calendar year, during the first two years following entry of this Decree.

Beginning two (2) years after entry of this Decree, the liquidated damages under this paragraph shall increase to twenty thousand dollars ($20,000.00) for each incomplete numbered step, per business day (calculated as provided above). In that event, the amount of liquidated damages imposed under this paragraph for the relevant six-month period will not exceed five (5) million dollars ($5,000,000.00).

Beginning two and a half (2.5) years after entry of the Decree, the liquidated damages under this paragraph shall increase to thirty thousand dollars ($30,000.00) for each incomplete numbered step, per business day (calculated as provided above). In that event, the amount of liquidated damages

imposed under this paragraph will not exceed ten (10) million dollars ($10,000,000.00) in any one calendar year.

In addition, if one or more numbered steps in the work plan described in Paragraph 5.C remain incomplete on the date set forth in the FDA-approved timetable for completion of the last numbered step, FDA may order TCVS to pay the United States Treasury equitable disgorgement in the amount of 7.4% of the Product Revenue generated by Cardiovascular Devices manufactured prior to successful completion of the work plan as determined by FDA under Paragraph 5.G.

20. The remedy under Paragraphs 18 and 19 shall be in addition to any other remedies available to the United States under this Decree or the law. Defendants understand and agree that the imposition of liquidated damages and equitable disgorgement under Paragraphs 18 and 19 does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of liquidated damages or equitable disgorgement pursuant to Paragraphs 18 and 19.

21. Any equitable disgorgement amount(s) paid under Paragraph 19 shall be determined by an independent Certified Public Account (“CPA”), who shall be without personal or financial ties (other than the consulting agreement) to Defendants or their families and shall be paid by Defendants, and

such amount(s) shall be calculated on a quarterly basis beginning ninety (90) days after the requirement to make any payment is triggered. Defendants shall cause the CPA to send a written certification determining and explaining to FDA within forty-five (45) days of the end of each quarter, and payments shall be due and paid within twenty (20) days after the date on which the CPA sends the written determination and explanation to FDA.

22. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, TCVS shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

23. TCVS shall reimburse FDA for the costs of all FDA inspections; sampling; testing; travel; time spent traveling, reviewing documents, consulting with Defendants' CGMP and data quality auditors and certified public accountants, and supervising this Decree; and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such activities shall be borne by TCVS at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection or investigative work; $104.96 per hour or fraction thereof per representative for analytical or

review work; $0.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

24. The parties acknowledge that the payment(s) under this Decree are not a fine, penalty, forfeiture, or payment in lieu thereof.

GENERAL PROVISIONS

25. TCVS agrees that Steven M. Arick will not participate in any way in any decisions affecting TCVS's policies regarding the filing of MDRs with FDA or the implementation of those policies.

26. All FDA orders issued under this Decree shall be issued and signed by the District Director of the Detroit District Office or her/his designee.

27. This Decree resolves only those claims set forth in the Complaint in this action, and does not affect any other civil, criminal, or administrative claims that the government may have or bring in the future against the Defendants herein.

28. If any deadline in this Decree falls on a weekend or federal holiday, the deadline shall be continued to the next business day.

29. The parties may at any time petition each other in writing to modify any deadline provided herein, and if the parties mutually agree in writing to modify a deadline, such extension may be granted without seeking leave of Court.

30. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered under this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

31. If Defendants have maintained the Ann Arbor Facility in a state of continuous compliance with applicable laws and regulations for at least sixty (60) months after satisfying all of their obligations under Paragraph 5, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such petition.

32. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying

this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

This 29th day of March, 2011.

/s/ Victoria A. Roberts
UNITED STATES DISTRICT JUDGE

FOR THE DEFENDANTS:

w/consent of Mark Sutter
TERUMO CARDIOVASCULAR SYSTEMS CORPORATION

FOR THE PLAINTIFF:

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Individually, and as President and Chief Executive Officer of Terumo Cardiovascular Systems Corporation

s/with consent of Mark Lincoln
MARK LINCOLN
Individually, and as Vice President of Quality Assurance and Operations of Terumo Cardiovascular Systems Corporation

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s/w/consent of Robert A. Dormer
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Washington, D.C. 20005

Attorney for Defendant
Mark Lincoln

Index of Exhibits
USA v. Terumo Cardiovascular Systems

Exhibit	Description
1	Notification Guide
2	Terumo Advanced Perfusion System Chart

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Terumo Cardiovascular Systems Corporation

NOTIFICATION GUIDE

[DATE]

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TABLE OF CONTENTS

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INTRODUCTION

Terumo Cardiovascular Systems Corporation (Terumo CVS) is providing this Notification Guide to inform you about changes in the availability of certain products as a result of entering into a Consent Decree of Permanent Injunction (Decree) with the United States Food and Drug Administration (FDA).

The guide also provides you with instructions for continuing to receive uninterrupted product support for most of the Terumo CVS products you currently use.

We apologize for any inconvenience that this may cause you and your staff. Your Terumo CVS Sales representative is available to assist with any issues that may arise during the period some products are unavailable.

In addition, for our U.S. users, Terumo CVS Customer Service is available to answer any questions at 1-800-521-2818, and a website with up-to-date information about the Decree can be found at www.terumo-cvs.com/consentdecree. For our International users, please contact your local Terumo distributor or refer to the website listed above. (See Appendix B for International office locations and contact information.)

Background

On [DATE], Terumo CVS entered into the Decree with the FDA. The action followed an inspection of Terumo CVS's Ann Arbor facility from January 4 to March 29, 2010, during which the FDA observed that the devices at the facility were not manufactured, processed, and designed in accordance with FDA's Quality System (QS) and Medical Device Reporting (MDR) regulations for medical devices. FDA found, among other things, that Terumo CVS had deficiencies in the areas of corrective and preventative action, nonconforming product, complaint handling, purchasing controls, process validation, and design controls.

Under the terms of the Decree, Terumo CVS must undertake certain corrective actions to comply with FDA regulations.

Product Restrictions

Also under the terms of the Decree, Terumo CVS must restrict the availability of some products manufactured at its Ann Arbor facility:

The Decree prohibits Terumo CVS from providing the CDI™ 101 Hematocrit/Oxygen Saturation Monitoring System until that device has been cleared by FDA (see page 5). This Guide provides a list of alternative products to use during the period the CDI 101 system is unavailable. **The Decree also prohibits Terumo CVS from providing the Tenderflow™ Pediatric Arterial Cannulae.** This guide lists available alternatives for this product.

The Decree permits Terumo CVS to continue to distribute other devices manufactured at Terumo CVS's Ann Arbor facility (see page 7) to support only existing users in the U.S. ("existing U.S. users") and existing first-level International distributors ("existing International distributors"). The term "support" is defined in the Decree to mean that Terumo CVS may provide only existing U.S. users and existing International distributors with the following for the particular device(s) owned by existing U.S. users or purchased by existing International distributors on or before [insert date of entry of Decree]: (1)

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ALTERNATIVE PRODUCT OPTIONS FOR RESTRICTED PRODUCTS

Under the terms of the Decree, Terumo CVS cannot provide the following products[1] to any person or entity at the present time:

- CDI™ 101 Hematocrit/Oxygenation Saturation Monitoring System

  NOTE: The disposable hematocrit/oxygen saturation cuvettes are available for use with existing CDI 101 systems or other CDI monitoring systems.
- TenderFlow™ Pediatric Arterial Cannulae

The following list of FDA-approved or cleared alternative products has been provided for your facility to consider for use during the period that the CDI 101 system and the TenderFlow™ Pediatric Arterial Cannulae are unavailable. The list is intended as a broad overview to assist facilities in independent decision-making, and not as a recommendation of any particular alternative product.

Alternatives for CDI™ 101 Hematocrit/Oxygenation Saturation Monitoring System

Medtronic – BioTrend® Oxygen Saturation and Hematocrit Monitor
Sorin Cobe – SAT/HCT monitor – Catalog No. 050-280-000
Spectrum Medical – System M – Model Code M2 or M3

Note: Terumo CVS also may provide CDI 500 loaner devices to replace CDI 101 devices until the CDI 101 has been cleared by FDA.

Alternatives for TenderFlow™ Pediatric Arterial Cannulae

Description	TenderFlow	Medtronic	Edwards	Maquet/Polystan
6 Fr, wire reinforced, vented ¼" connector	813567	77006		161406
6 Fr, wire reinforced, non-vented ¼" connector	813568	77106		
8 Fr, wire reinforced, vented ¼" connector	813569	77008		161408
8 Fr, wire reinforced, non-vented ¼" connector	813570	77108	PEDA008SB	
10 Fr, wire reinforced, vented ¼" connector	813571	77010		161410
10 Fr, wire reinforced, non-vented ¼" connector	813572	77110	PEDA010SB	
12 Fr, wire reinforced, vented ¼" connector	813573	77012		161412
12 Fr, wire reinforced, non-vented ¼" connector	813574	77112	PEDA012SB	
14 Fr, wire reinforced, vented ¼" connector	813575	77014		
14 Fr, wire reinforced, non-vented ¼" connector	813576	77114	PEDA014SB	
16 Fr, wire reinforced, vented ¼" connector	813577	77016		
16 Fr, wire reinforced, non-vented ¼" connector	813578	77116	PEDA016SB	

Products listed as alternatives may not be available in all markets and other alternatives may be available in some markets

[1] "Products" refers to all components and accessories that are dedicated for use with this system, unless otherwise noted.

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PRODUCTS AVAILABLE WITH RESTRICTION AND THE CERTIFICATE OF MEDICAL NECESSITY

Terumo CVS may continue to distribute certain devices to support only existing U.S. users and existing International distributors, provided that the authorized representatives of the existing U.S. users and/or existing International end-users have signed the attached CMN form certifying that, after learning of the FDA findings at the Terumo CVS Ann Arbor manufacturing facility and evaluating the relevant risks and benefits, they have deemed one or more of the devices to be an immediate and continuing medical necessity for their performance of cardiopulmonary bypass procedures. A list of these devices along with their associated parts, components, and accessories, collectively referred to as the "Products Available With Restrictions," includes the following products.[2]

- Heart Lung Machines:
  - Terumo® Advanced Perfusion System 1
  - Sarns™ Modular Perfusion System 8000
- Centrifugal System:
  - Sarns™ Centrifugal System

  Note: The Sarns™ Disposable Centrifugal Pump is available with no sales restriction
- Cooling and Heating Devices:
  - HX2™ Temperature Management System
  - Sarns™ TCMII Cooling and Heating System
- Interoperative Monitoring Systems:
  - CDI™ 500 Blood Parameter Monitoring System

  Note: Disposable shunt sensors and hematocrit/oxygen saturation cuvettes are available with no sales restriction.
- Sternal Saw:
  - Sarns™ Sternal Saw II System and Replacement Blades
- Data Management System:
  - T-Link™ Data Management System
- Cannulae and Catheters:
  - Cannulae for Cardiopulmonary Bypass
  - Cannulae for Cardioplegia Delivery
  - Vents, Suckers, Dilators, Connectors and Reducers

  Note: TenderFlow™ Pediatric Arterial Cannulae are not available.

Successful completion of a CMN form allows a facility to obtain support for the products identified above.

A copy of the CMN form is included in Appendix A to this Guide.

[2] "Products" refers to all components and accessories that are dedicated for use with a system, unless otherwise noted.

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PRODUCTS AVAILABLE WITHOUT RESTRICTION

The following products[3] that are not manufactured, processed, packed, installed, and/or labeled at the Ann Arbor facility and for which the facility conducts no post-marketing activities are exempted from any sales restrictions under the terms of the Decree:

Products Manufactured by Terumo CVS

- Oxygenation Systems and Accessories:
  - CAPIOX® SX Oxygenators
  - CAPIOX® RX Oxygenators
  - CAPIOX® FX Oxygenators
  - ROCSafe™ Hybrid Perfusion System
- Custom Tubing Packs

  Note: Tubing Packs that contain Terumo Cannulae are available with restrictions (see page 7).
- Disposable Centrifugal Pump
  - Sarns™ Disposable Centrifugal Pump
- Reservoirs:
  - CAPIOX® Flexible Venous Reservoirs
  - CAPIOX® Cardiotomy Reservior
- Myocardial Protection Products:
  - Sarns™ Cardioplegia Sets with Conducer Heat Exchanger and MP-4™ Monitoring Module
  - Sarns™ Cardioplegia Sets with PVC Coil and MP-4™ Monitoring Module
  - Sarns™ Cardioplegia Sets with Conducer Heat Exchanger and Bubble Trap
  - Sarns™ Cardioplegia Sets with PVC Coil and Bubble Trap
  - CAPIOX® CP50 Cardioplegia Set
- Filters:
  - Terumo® AL6X Arterial Blood Line Filter
  - Terumo® AL8X Arterial Blood Line Filter
  - CAPIOX® Arterial Line Filters
- Bubble Traps:
  - CAPIOX® Bubble Traps
- Endoscopic Vein Harvesting:
  - VirtuoSaph® Endoscopic Vein Harvesting System
  - VirtuoSaph® Plus Endoscopic Vessel Harvesting System
  - Terumo® Endoscope
  - Generator, Endoscopic Tower Components, Sterilization Trays

[3] "Products" refers to all components and accessories that are dedicated for use with a system, unless otherwise noted.

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Products distributed by Terumo CVS

- Continuous Autotransfusion System:
  - Fresenius C.A.T.S Continuous AutoTransfusion System
- Platelet Therapy:
  - SmartPReP® 2 Platelet Concentrate System
  - Pall Filters for use in Cardiopulmonary Bypass
  - Minntech® Hemocor® HPH Hemoconcentrators

Products Manufactured by other Terumo Companies

- Terumo Medical Corporation
- Terumo Interventional Systems, a business unit of Terumo Medical Corporation
- Terumo Heart Inc.
- Vascutek Ltd.
- MicroVention, Inc.

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INSTRUCTIONS FOR EXISTING USERS REGARDING CERTIFICATE OF MEDICAL NECESSITY

On [DATE], Terumo Cardiovascular Systems Corporation, Terumo CVS, entered into a Consent Decree of Permanent Injunction (Decree) with the U.S. Food and Drug Administration (FDA). The Decree permits Terumo CVS to continue to distribute certain Terumo CVS device(s) identified below to support only existing users in the U.S. ("existing U.S. users") and existing first-level distributors outside of the U.S. ("existing International distributors"), provided that you owned or purchased the particular device to be supported before [insert date of entry of Decree]. The term "support" is defined in the Decree to mean that Terumo CVS may provide only existing U.S. users and existing International distributors with the following for the particular device(s) owned by existing U.S. users or purchased by existing International distributors on or before [insert date of entry of Decree]: (1) service and maintenance; (2) replacement devices (including parts, components, and accessories), and (3) loaner devices. **Terumo CVS may not sell and/or distribute any device to any existing International distributor unless the device is intended for an existing overseas facility, hospital, and/or group of perfusionists or surgeons ("existing International end-user") that already owned such a device prior to [insert date of entry of decree]**

To receive such support for the products identified below:

- An authorized representative of the existing U.S. user or International end-user must sign the Certificate of Medical Necessity (CMN) form certifying that, after s/he has learned of the FDA's findings at the Terumo CVS Ann Arbor manufacturing facility and evaluated the benefits and risks associated with using the device(s), s/he deems the device(s) to be an immediate and continuing medical necessity for the user's performance of cardiovascular bypass procedures.
- The CMN form must be signed by one of the following individuals: Chief Executive Officer, President, Chief Medical Officer, Chief Operating Officer, Director of the Operating Room, Chief Perfusionist, or Hospital Administrator.
- Existing U.S. users must provide the completed CMN form to Terumo CVS as soon as possible, but no later than [DATE], prior to receiving any support. Existing International end-users must provide the completed CMN form to either their local distributor or Terumo office prior to receiving any support.
  - U.S. users, please return the completed CMN form to Terumo CVS at:
    - 6200 Jackson Road, Ann Arbor, MI 48103
    - Or fax to: 1-800-292-6551 or 734-663-4145
    - Or PDF via email to: cvscustomerservice@terumomedical.com
  - International end-users, please return the completed CMN form to your local distributor or the closest Terumo office (see Appendix B for office locations and contact information)

If the form is incomplete, or if the existing U.S. user does not return the form by [DATE], we will be unable to accept your CMN and will not be able to continue to support the above-listed products at your facility. Nor may we continue to support any existing International end-user if the end-user does not return a properly completed form to Terumo CVS prior to receiving any support. Your Terumo sales representative will be contacting you to assist in completing the CMN form, and discuss any additional questions you may have.

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Appendix A:

CERTIFICATE OF MEDICAL NECESSITY (CMN) FORM U.S. USERS

Provide the following information:

User name (institution or hospital): _____

Address: _____

City: _____ State: _____ Zip: _____

After reading the [DATE] user notification guide regarding the FDA findings at the Terumo CVS Ann Arbor manufacturing facility, I certify that this medical facility evaluated the relevant risks and benefits and concluded that it has an immediate medical need for the continued use and purchase of the above-listed Terumo CVS products and their associated parts, components, and accessories, because these products are necessary for us to perform cardiovascular bypass procedures.

Authorized Signature: _____

Institution/Hospital: _____

Name (print): _____

Title: _____

Date: _____

Telephone: _____

E-mail (if available): _____

Please return the completed CMN form to Terumo CVS at:

- 6200 Jackson Road, Ann Arbor, MI 48103
- Or fax to: 1-800-292-6551 or 734-663-4145
- Or PDF via email to: cvscustomerservice@terumomedical.com

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Appendix A:

CERTIFICATE OF MEDICAL NECESSITY (CMN) FORM INTERNATIONAL USERS

Provide the following information:

User name (institution or hospital): _____

Address: _____

City: _____ Country: _____

After reading the [DATE] user notification guide regarding the FDA findings at the Terumo CVS Ann Arbor manufacturing facility, I certify that this medical facility evaluated the relevant risks and benefits and concluded that it has an immediate medical need for the continued use and purchase of the above-listed Terumo CVS products and their associated parts, components, and accessories, because these products are necessary for us to perform cardiovascular bypass procedures.

Authorized Signature: _____

Institution/Hospital: _____

Name (print): _____

Title: _____

Date: _____

Telephone: _____

E-mail (if available): _____

Please return the completed CMN form to your local distributor or the closest Terumo office (see Appendix B for office locations and contact information).

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Appendix B:

Global Sales and Support – Europe

- **Terumo Europe N.V.**
  Interleuvenlaan 40
  3001 Leuven, Belgium
  Tel: +32 16 38 12 11
  Fax: +32 16 40 02 49
- **Terumo Europe N.V. Cardiovascular Systems Liaison Office**
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  65760 Eschborn, Germany
  Tel.: +49 6196 8023 500
  Fax: +49 6196 8023 555
- **Terumo Deutschland GmbH**
  Ludwig-Erhard-Strasse 6
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  Tel: +49 6196 80 230
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  Tel: +41 56 419 10 10
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TERUMO

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Terumo Advanced Perfusion System 1

	Part Number	Component
Safety/Interface Modules	802110	Air Detector Module
	802111	Level Detector Module
	802112	Pressure Pod APS
	802114	Temperature Pod APS
	802558	Interface Module CDI 100
	815682	Serial Adapter (DB9M-DB9M)
	803479	Interface Module CDI 500
	804981	Cable Assembly 100/500 Mod APS
	802113	Data Transfer Serial 232
	803518	Data Transfer Serial 485
Safety Accessories	195215	Yellow Level Detector II Cable
	195274	Red Level Detector II Cable
	195240	Level Detector II Pads & Gel
	5773	5773 Air Sensor 3/8 x 3/32
	5791	5791 Air Sensor 1/4 x 1/32
	5785	5785 Air Sensor 1/4 x 1/16
	16433301	Pressure Transducer
	22300030	Pressure transducer holder
	16066100	Pressure Monitoring Kit
	12100	Clip-on temperature probe
	12110	Disposable metal temperature connector, 3/8" x 3/8"
	13406	Disposable metal temperature connector
	13408	Disposable metal temperature connector
	6690	Single port, 3/16" ID x 1/16" wall tubing
	6691	Single port, 1/4" ID x 1/16" wall tubing
	164278	Flow Sensor Gel
Poles/Brackets/Lamps	16431701	Telescoping Poles
	16426	8K Crossbar Kit, 3'
	16553301	2' Pole
	131115	3' pole
	16553401	4' Pole
	145980	Crossbar Fitting
	801093	Aux Pump Mount Brkt - Inline
	816483	Descending Pole Mount Bracket
	816477	Dual Pumps Pole Mount Bracket
	816620	Flexible Mounting Arm
	804372	Pole Mount Bracket Cent Control
	801550	Flow Pod Bracket
	5793	UAS Bracket
	816489	System 1 Shelf
	816370	System 1 Sliding Back Cover Panel
	4404	9000 Pole mounted writing surface
	16434101	Instrument Tray
	149892	Cable Assembly Lemo
	149876	Holder Sensor UAS
	143554	6 in. adapter cord - auxiliary outlet to receptacle
	801238	Lamp, Long Neck APS
	801558	Lamp, Short Neck APS
	801139	Holder for reservoir (short arm).

	816173	Flexible venous reservoir holder, short arm.
	816181	Flexible venous reservoir holder, long arm.
	816185	Volume control grid.
	801804	CAPIOX SX/RX/FX oxygenators with hard shell reservoir holder.
	812613	Holder for CAPIOX® RX25/FX25 oxygenators.
	812614	Holder for CAPIOX® RX15/FX15 oxygenators.
	801327	SXRMID middle arm for CAPIOX SX/RX oxygenator holder.
	804992	Holder for Reduced Prime Perfusion Circuit.
	4979	Water supply bracket for Sarns Conducer Heat Exchanger.
	9442	Accessory kit, for sets with Conducer cardioplegia heat exchanger.. Use as starter kit. Includes water supply bracket (4979), bubble trap holder (147651), thumbscrew (131094) and 5/8" pole adapter (8144010)
	9456	Water seal replacement.
	147651	Bubble trap holder. Order 147651, 150957, and 8144010 for complete bubble trap mounting bracket
	150957	2" thumbscrew. (Order 147651, 150957, and 8144010 for complete bubble trap mounting bracket)
	8144010	Pole adapter, 5/8". Order 147651, 150957, and 8144010 for complete bubble trap mounting bracket
	9441	Accessory kits, for sets with Conducer cardioplegia heat exchanger and MP-4 monitoring module.. Use as starter kit. Includes water supply bracket (4979) and holder for MP-4 monitoring module (16529701)
	16529701	Holder for Sarns MP-4 monitoring module.
	16436	Cardioplegia bucket.
	16437	Cardioplegia bucket holder.
	16438	Accessory kit for sets with PVC Coil and MP-4 monitoring module.. Use as starter kit. Includes MP-4 module holder (16529701), thermal bucket (16436) and holder(16437)
GAS BLENDERS/Connectors	801188	EPGS System
	164235	Blender
	9497	Triple Gas Flowmeter O2/O2/CO2
	814475	U.S. Hose Kit Air, O2,CO2
	144207	NCG Hose Adpater Set
	144215	DISS Hose Adapter Set
	144223	Ohio Diamond Hose Adapter Set
Adding ROLLER PUMPS	816571	System 1 6" Roller Pump
	816570	System 1 4" Roller Pump
	801040	System 1 6" Roller Pump (Blue)
	801041	System 1 4" Roller Pump (Blue)
Adding CENTRIFUGAL PUMP	816572	System 1 Centrifugal Control Module
	801046	System 1 Centrifugal Control Module (white)
	164267	Centrifugal Drive Motor
	164268	Delphin Manual Drive
	802018	Flow Pod APS

	6382	Centrifugal TOF Flow Sensor
New CCM (B)	816300	Central Control Monitor
	816261	CCM Cover
OCCLUDER	803480	Occluder Pod APS
	806455	Occluder Head
Operators Manual	802350	System 1 Operators Manual
TLink™ Data Management System	814806	Touch screen small tray bracket.
	814808	Single port serial converter.
	814850	TLink™ Data Management System.
	814851	TLink™ System touch screen computer.
	814852	Notebook computer.
	814853	Desktop computer.
	814854	Serial converter hub (10 port).
	814855	Touch screen large tray bracket.
	814856	Notebook large tray bracket.
	814857	Touch screen mounting bracket.
	814858	Extension pole mount bracket.
	814859	Notebook keyboard cover.
	814860	6ft RS232 cable (DB9M-DB9F).
	814861	15ft RS232 cable (DB9M-DB9F).
	814862	50ft RS232 cable (DB9M-DB9F).
	814863	Serial adapter (DB9M-DB25F).
	814864	Mini-keyboard.
	814866	Serial adapter (DB25F-DB25F).
	814867	Serial adapter (DB9F-DB9F).
	814868	Serial adapter (DB25M-DB25M).
	814869	Barcode wand scanner.
	814870	Touch screen stylus.
	814871	TLink™ Data Management Software license.
	815677	Standard keyboard.
	815678	Standard keyboard cover.
	815681	4 port USB hub extension (converts 1 USB port to 4 USB ports).
	815682	Serial adapter (DB9M-DB9M).
	815683	25ft RS232 cable (DB9M-DB9F).
	815684	6ft RS485 cable (DB9M-DB9F).
	815685	15ft RS485 cable (DB9M-DB9F).
	815686	25ft RS485 Cable (DB9M-DB9F).
	815687	50ft RS485 cable (DB9M-DB9F).
	815689	Notebook small tray bracket.
	815804	Barcode laser scanner.
	815805	Barcode laser scanner holder (required with 815804).
	815820	Microsoft® Office standard.
	816093	7ft Cat5E shielded cable (RJ45-RJ45).
	816094	15ft Cat5E shielded cable (RJ45-RJ45).
	816095	25ft Cat5E shielded cable (RJ45-RJ45).
	816096	50ft Cat5E shielded cable (RJ45-RJ45).
	816098	TLink™ DMS adapter (DB9F-RJ45).
	816099	8000/101/500 adapter (DB9M-RJ45).
	816100	CDI100 adapter (DB9F-RJ45).
	816101	Centrifugal adapter (DB9F-RJ45).

816102	GE Datex S5 adapter (DB9F-RJ45).
816103	System 1/other adapter (DB9M-RJ45).
816104	9000 adapter (DB25M-RJ45).
816295	HP/Agilent/Philips CMS adapter (DM25M-RJ45).
816297	GEM/INVOS adapter (DB9F-RJ45).
816298	HP/Agilent/Philips CMS adapter (DM25F-RJ45).
816426	Philips IntelliVue adapter (RJ45-DB9F).

*orange color indicates common accessories of both System 1 and System 8000

Sarns Perfusion System 8000

	Part Number	Component
Safety Monitors/Battery	16413	Arterial Monitor
	16414	Cardioplegia Monitor
	16422	Battery Module 115V
	16415	Battery Module 220/240V
	16423	Battery Module 100V
Safety Accessories	195215	Yellow Level Detector II Cable
	195274	Red Level Detector II Cable
	195240	Level Detector II Pads & Gel
	5773	5773 Air Sensor 3/8 x 3/32
	5791	5791 Air Sensor 1/4 x 1/32
	5785	5785 Air Sensor 1/4 x 1/16
	16433301	Pressure Transducer
	22300030	Pressure transducer holder
	16066100	Pressure Monitoring Kit
	146835	Tube Clamp Assembly
	6072	Tube clamp pump inserts for Sarns Roller pumps, 1/4" ID x 1/16" wall thickness, black
	6073	Tube clamp pump inserts for Sarns Roller pumps, 1/4" ID x 3/32" wall thickness, gold
	6074	Tube clamp pump inserts for Sarns Roller pumps, 3/8" ID x 1/16" wall thickness, dark green
	6075	Tube clamp pump inserts for Sarns Roller pumps, 3/8" ID x 3/32" wall thickness, red
	6079	Tube clamp pump inserts for Sarns Roller pumps , 5/8" ID x 1/16" wall thickness, silver
	6080	Tube clamp pump inserts for Sarns Roller pumps, 1/2" ID x 3/32" wall thickness, silver
	6077	Tube clamp pump inserts with screws for Sarns 1:1 cardioplegia set, white
	164195	Tube clamp pump inserts with screws for Sarns, 2:1 cardioplegia set, tan
	164190	Tube clamp pump inserts with screws for Sarns 4:1 cardioplegia set, blue
	5588	Tube clamp pump inserts with screws for Sarns, 8:1 cardioplegia set, red
	16417	Communications Module
	16416	Pulsatile Flow Control Module
	12100	Clip-on temperature probe
	12110	Disposable metal temperature connector, 3/8" x 3/8"
	13406	Disposable metal temperature connector
	13408	Disposable metal temperature connector
	6690	Single port, 3/16" ID x 1/16" wall tubing
	6691	Single port, 1/4" ID x 1/16" wall tubing
	164278	Flow Sensor Gel
Poles/Brackets/Lamps	16431701	Telescoping Poles
	16426	8K Crossbar Kit, 3'
	16427	8K Crossbar Kit, 5 Pump Base

16553301	2' Pole
131115	3' pole
16553401	4' Pole
145980	Crossbar Fitting
16505801	Short Mounting Arm
16505901	Long Mounting Arm
16425	Extension Arm
816620	Flexible Mounting Arm
5793	UAS Bracket
4404	Pole mounted writing surface
16434101	Instrument Tray
149892	Cable Assembly Lemo
149876	Holder Sensor UAS
143554	6 in. adapter cord - auxiliary outlet to receptacle
134332	Sarns Centrifugal Cable to System 8000
16420	Halogen Lamp, Short
7278	Halogen Lamp, Long
801139	Holder for reservoir (short arm).
816173	Flexible venous reservoir holder, short arm.
816181	Flexible venous reservoir holder, long arm.
816185	Volume control grid.
801804	CAPIOX SX/RX/FX oxygenators with hard shell reservoir holder.
812613	Holder for CAPIOX® RX25/FX25 oxygenators.
812614	Holder for CAPIOX® RX15/FX15 oxygenators.
801327	SXRMID middle arm for CAPIOX SX/RX oxygenator holder.
804992	Holder for Reduced Prime Perfusion Circuit.
4979	Water supply bracket for Sarns Conducer Heat Exchanger.
9442	Accessory kit, for sets with Conducer cardioplegia heat exchanger.. Use as starter kit. Includes water supply bracket (4979), bubble trap holder (147651), thumbscrew (131094) and 5/8" pole adapter (8144010)
9456	Water seal replacement.
147651	Bubble trap holder. Order 147651, 150957, and 8144010 for complete bubble trap mounting bracket
150957	2" thumbscrew. (Order 147651, 150957, and 8144010 for complete bubble trap mounting bracket)
8144010	Pole adapter, 5/8". Order 147651, 150957, and 8144010 for complete bubble trap mounting bracket
9441	Accessory kits, for sets with Conducer cardioplegia heat exchanger and MP-4 monitoring module.. Use as starter kit. Includes water supply bracket (4979) and holder for MP-4 monitoring module (16529701)
16529701	Holder for Sarns MP-4 monitoring module.
16436	Cardioplegia bucket.
16437	Cardioplegia bucket holder.

	16438	Accessory kit for sets with PVC Coil and MP-4 monitoring module.. Use as starter kit. Includes MP-4 module holder (16529701), thermal bucket (16436) and holder(16437)
GAS BLENDERS/Connectors	164235	Blender
	9497	Triple Gas Flowmeter O2/O2/CO2
	814475	U.S. Hose Kit Air, O2,CO2
	144207	NCG Hose Adpater Set
	144215	DISS Hose Adapter Set
	144223	Ohio Diamond Hose Adapter Set
Adding ROLLER PUMPS	16402	Roller Pump 1115V
	16407	Roller Pump 220V
	16411	Rolller Pump 100V
Adding CENTRIFUGAL PUMP	6379	Centrifugal Control Module 100/115V
	6380	Centrifugal Control Module 220/240V
	164267	Centrifugal Drive Motor
	164268	Delphin Manual Drive
	9490	Battery 100/115V
	9491	Battery 220/240V
	6382	Centrifugal TOF Flow Sensor
OCCLUDER	16418	8000 Venous Line Occluder
Operator Manuals	802073	Centrifugal System Operators Manual
	802071	Air Bubble Detector Operators Manual
	135271	System 8000 Operators Manual
TLink™ Data Management System	814806	Touch screen small tray bracket.
	814808	Single port serial converter.
	814850	TLink™ Data Management System.
	814851	TLink™ System touch screen computer.
	814852	Notebook computer.
	814853	Desktop computer.
	814854	Serial converter hub (10 port).
	814855	Touch screen large tray bracket.
	814856	Notebook large tray bracket.
	814857	Touch screen mounting bracket.
	814858	Extension pole mount bracket.
	814859	Notebook keyboard cover.
	814860	6ft RS232 cable (DB9M-DB9F).
	814861	15ft RS232 cable (DB9M-DB9F).
	814862	50ft RS232 cable (DB9M-DB9F).
	814863	Serial adapter (DB9M-DB25F).
	814864	Mini-keyboard.
	814866	Serial adapter (DB25F-DB25F).
	814867	Serial adapter (DB9F-DB9F).
	814868	Serial adapter (DB25M-DB25M).
	814869	Barcode wand scanner.
	814870	Touch screen stylus.
	814871	TLink™ Data Management Software license.
	815677	Standard keyboard.
	815678	Standard keyboard cover.
	815681	4 port USB hub extension (converts 1 USB port to 4 USB ports).

815682	Serial adapter (DB9M-DB9M).
815683	25ft RS232 cable (DB9M-DB9F).
815684	6ft RS485 cable (DB9M-DB9F).
815685	15ft RS485 cable (DB9M-DB9F).
815686	25ft RS485 Cable (DB9M-DB9F).
815687	50ft RS485 cable (DB9M-DB9F).
815689	Notebook small tray bracket.
815804	Barcode laser scanner.
815805	Barcode laser scanner holder (required with 815804).
815820	Microsoft® Office standard.
816093	7ft Cat5E shielded cable (RJ45-RJ45).
816094	15ft Cat5E shielded cable (RJ45-RJ45).
816095	25ft Cat5E shielded cable (RJ45-RJ45).
816096	50ft Cat5E shielded cable (RJ45-RJ45).
816098	TLink™ DMS adapter (DB9F-RJ45).
816099	8000/101/500 adapter (DB9M-RJ45).
816100	CDI100 adapter (DB9F-RJ45).
816101	Centrifugal adapter (DB9F-RJ45).
816102	GE Datex S5 adapter (DB9F-RJ45).
816103	System 1/other adapter (DB9M-RJ45).
816104	9000 adapter (DB25M-RJ45).
816295	HP/Agilent/Philips CMS adapter (DM25M-RJ45).
816297	GEM/INVOS adapter (DB9F-RJ45).
816298	HP/Agilent/Philips CMS adapter (DM25F-RJ45).
816426	Philips IntelliVue adapter (RJ45-DB9F).

*orange color indicates common accessories of both System 1 and System 8000

Blood Parameter Monitoring

	Part Number	Component
CDI 101 Hematocrit/Oxygen Saturation Monitor Accessories	7101	Interface module with hematocrit/oxygen saturation probe
	7103	Interface cable, 2' (61 cm)
	7203	Interface cable, 9.5' (2.9m)
	7204	Printer paper (5/case)
	7206	Pole clamp
	7202	Flash card
	6914	H/S cuvette 1/4" x 1/4" (20/case)
	6913	H/S cuvette 3/8" x 3/8" (20/case)
	6912	H/S cuvette 1/2" x 1/2" (20/case)
	6934	H/S cuvette 1/4" x 1/4" with 6" (15.2 cm) extension tube (10/case)
	6933	H/S cuvette 3/8" x 3/8" with 6" (15.2 cm) extension tube (10/case)
	6932	H/S cuvette 1/2" x 1/2" with 6" (15.2 cm) extension tube (10/case)
	6924	H/S cuvette 1/4" x 1/4 ", bulk non-sterile
	6923	H/S cuvette 3/8" x 3/8 ", bulk non-sterile
	6922	H/S cuvette 1/2" x 1/2 ", bulk non-sterile
	188921	H/S spring clip assembly
	417279	Operator's manual
	403133	Power Cord (110/120V)
	819659	Power Cord (220/240V)
CDI 500 Blood Parameter Monitoring System Accessories	540	Calibrator
	CDI506	Gas A, calibration gas for use with calibrator 540
	CDI507	Gas B, calibration gas for use with calibrator 540
	7310	Printer paper
	CDI517	Monitor pole clamp
	CDI518	Monitor pole clamp
	CDI519	Cable head bracket
	CDI510H	Shunt sensor for use with System 500, heparin treated (20/case)
	SCDI510H	Shunt sensor for use with System 500, heparin treated, single
	158502	Shunt extension lines
	145066	1/4" shunt bypass lines
	145074	3/8" shunt bypass lines
	145058	1/2" shunt bypass lines
	6914	H/S cuvette 1/4" x 1/4" (20/case)
	6913	H/S cuvette 3/8" x 3/8" (20/case)
	6912	H/S cuvette 1/2" x 1/2" (20/case)
	6934	H/S cuvette 1/4" x 1/4" with 6" (15.2 cm) extension tube (10/case)
	6933	H/S cuvette 3/8" x 3/8" with 6" (15.2 cm) extension tube (10/case)
	6932	H/S cuvette 1/2" x 1/2" with 6" (15.2 cm) extension tube (10/case)
	6924	H/S cuvette 1/4" x 1/4 ", bulk non-sterile
	6923	H/S cuvette 3/8" x 3/8 ", bulk non-sterile
	6922	H/S cuvette 1/2" x 1/2 ", bulk non-sterile
	16417	Sarns 8000 communications module
	151829	Cable, 8000 to 500 (pump flow interface)
	154481	Cable, 9000 to 500 (pump flow interface)
	158810	Cable, 500 to 9000 RS232 male
	151853	Cable, centrifugal to 500
	151861	Cable, Medtronic 550 to 500

	158828 Cable, Jostra HL20 to 500
	158801 Cable, Stockert SIII/SC to 500
	804981 Cable, CDI 100/101/500 to System 1 CDI module
	804982 Cable from remote communication to RS232 module or RS485 module
	188921 H/S spring clip assembly
	145891 BPM
	145883 HSAT
	236603 Operator's manual
	131916 Power Cord
	143554 Universal Adapter Cord - 6"
	202198 Box
	162860 Insert foam, top
	162878 Insert foam, bottom
	184452 Bag with zipper
	164478 Dessicant
CDI 100 Hematocrit/Oxygen Saturation Monitor Accessories	
	151976 H/S spring clip assembly
	235598 Box
	158713 Insert foam, top
	158721 Insert foam, bottom
	195821 Operator's Manual

Heater/Cooler Accessories

HX2/TCMII/DCH	131086	Water Fitting Straight
	131078	Water Fitting Right Angle
	9439	Water Fitting CPG Heat Exchanger
	15746	Remote TCM II
	802014	TCM II Operators Manual
	146595	Main Accessory Kit TCM II
	146608	CPG Accessory Kit TCM II
	146616	Blanket Accessory Kit TCM II
	802261	DCH Operators Manual
	809883	Set up kit HX2
	817705	Chlorine Test Strips
	812220	Operators Manual HX2